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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,797	09/13/2001	John Walker	017227-0175	9643
22428	7590	11/10/2003	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

857,797

Applicant(s)

WALKER

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☒ Responsive to communication(s) filed on \_\_\_\_\_.
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 1-2, 4-18, 20 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-2, 4-18, 20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Applicable Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).
- \*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Amendment of 7/18/03 has been entered; claims 1—2, 4—8 and 20 are pending and under examination.

Claims 1-2, 4-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner has no idea what the invention is as now claimed. Claim 1 now recites, "the saponin component comprises a saponin and a sterol." Is the "sterol" component mixed with the saponin, or is the "sterol" a moiety covalently attached to the saponin? Examiner finds no such phrase anywhere in the disclosure; the most relevant portion that the examiner can ascertain from applicant's remarks would be page 10. Therein applicant refers to Quil A (a saponin component) and cholesterol (a "sterol") component as separate components that, along with phospholipids and protein form an immunostimulating complex. The examiner thus fails to comprehend how applicant considers that the saponin component (Quil A) could comprise both itself and a "sterol" (cholesterol), since these two entities have been listed as separate components at page 10.

Furthermore, claim 2 is incomprehensible in relation to base claim 1, by virtue of reciting "wherein the saponin component is an immunostimulating complex." Is it part of the saponin component, or is it an additional component that forms the immunostimulating complex? Like considerations apply to the "cholesterol" component of further dependent claim 7.

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Claims 1-2, 4-18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 1 recites new matter by virtue of reciting "the saponin component comprises a saponin and a sterol".

As noted supra, under indefiniteness, the examiner has failed to find any description at page 10 ~~f~~For the "sterol" component (cholesterol) being considered as a part of the "saponin" component, as opposed to merely being another component, along with the saponin, that forms an immunostimulating complex.

Also, if page 10 is what provides support for reciting "sterol", the single disclosed species of cholesterol utterly fails to support recitation of the new genus of "sterols".

In the herein below consideration of the prior art, amended claim 1 is interpreted to mean that the "sterol" component of the "saponin" is employed to form the "immunostimulating complex" of claim 2.

Applicant's amendment has overcome the previously stated 102 rejections over James et al., Edgar et al. and Moss et al.

The following prior art rejection(s) under 103 are maintained, or newly stated due to applicant's amendment.

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Claims 1-2, 4-7, 13-14 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. or Moss et al. either in view of MacKenzie et al.

James et al. and Moss et al. were previously cited under 102 against claims 1, 3-5; 13-14 and 17-19. The examiner noted therein that James et al. teach an adjuvant containing DEAE dextrin (an ionic polysaccharide component) and a saponin. Applicant's recitation of: ionic polysaccharide" (incorporated from original claim 3) in lieu of "ionic macromolecule" in claim 1 thus does not overcome the prior art.

Applicant's amendment has also inserted, into claim 1, the limitation that "the saponin comprises a saponin and a sterol." The examiner previously noted (103 rejection at page 6) that MacKenzie shows the further feature of providing the saponin adjuvant component in an immunostimulating (or ISCOM) matrix (same as applicant's "immunostimulating complex" disclosed at specification page 10). This ISCOM matrix includes a sterol, such as cholesterol, as a component. MacKenzie et al. show precisely the same components (e.g. abstract, and col. 1, lines 44-50) in their ISCOM matrix, as applicant shows in his immunostimulating complex. The examiner previously stated motivation from MacKenzie et al. for providing the saponin in an ISCOM matrix. Thus applicant's amendment of claim 1 has done nothing to overcome the combination of James et al. or Moss et al. in view of MacKenzie et al. (all references previously cited).

Applicant's comments regarding the previously stated 103 rejection that relied upon MacKenzie et al. have noted that the examiner did not reject claim 3 (now incorporated into claim 1) over the combination of references and that thus the rejection has been overcome. This argument is erroneous, because, in the previously stated rejection, claims 2 and 6-7 depended from claim 1, claim 3; claim 3 had already been rejected under 102 over both primary references.

Applicant has also urged that Moss et al. teach a solid vaccine and that MacKenzie et al. teach a solution/liquid vaccine and that the combination of references is improper. The examiner finds this unconvincing because the solid vaccines of Moss et al. were prepared from solutions/liquids (e.g. via lyophilization). Since Moss et al. had to prepare a liquid vaccine, in route to forming a solid vaccine, the teachings of MacKenzie et al. regarding liquid vaccines are applicable to Moss et al.

Furthermore, even if it were granted that applicant is correct, in that Moss et al.'s and MacKenzie et al.'s teachings are uncombinable, applicant's urgings in this regard would fail to overcome the combination of James et al. and MacKenzie et al.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. or Moss et al., either in view of MacKenzie et al. as applied to claims 1 and 13-14 above, and further in view of McNamara.

As noted in the previous office action (page 5), McNamara teaches the further feature of providing a LHRH peptide conjugated to diphtheria toxoid. He

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teaches that such LHRH conjugated are more immunogenic and more effective in fertility control than are previously provided conjugates of LHRH and carrier proteins. See page 9, lines 1-6. One would hence have been motivated to use a LHRH-diphtheria toxoid conjugate, as taught by McNamara et al., in lieu of the LHRH-protein conjugates of James et al. or Moss et al.

Applicant's response has traversed the 103 rejection employing McNamara on the basis that he considers that the amendment has overcome all rejections of independent claim 1. Because claim 1 has been rejected supra under 103, claim 15 remains rejected.

Applicant's urgings filed 7/15/03 have been considered but are unconvincing of patentability.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday through Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Saunders:jmr

October 31, 2003

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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